

K023415

p. 1/2

**DYNALOK CLASSIC™ Spinal System
510(k) Summary**

October 2002

DEC 13 2002

- I. **Company:** Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133
- II. **Proposed Proprietary Trade Name:** DYNA-LOK CLASSIC™ Spinal System
- III. **Regulation Name:** Spinal Interlaminar Fixation Orthosis, Spinal Intervertebral Fixation Orthosis, Pedicle Screw Spinal System
- IV. **Regulation Number:** 888.3050, 888.3060, 888.3070
- V. **Description:** The DYNALOK CLASSIC™ Spinal System consists of a variety of shapes and sizes of plates, bolts, screws, washers, nuts, spacers, CROSSLINK® Plates, and connecting components. The DYNALOK CLASSIC™ Spinal System components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. Additionally, the DYNALOK CLASSIC™ Spinal System may be used in conjunction with TSRH ® Spinal System, CD HORIZON ® Spinal System, and TENOR™ Spinal System.

DYNALOK CLASSIC™ Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ISO 5832-1 or ISO 5832-9. Alternatively, the entire system may be made out of medical grade titanium alloy described by such standards as ASTM F136 or ISO 5832-3. **Never use stainless steel and titanium implant components in the same construct.**

Medtronic Sofamor Danek expressly warrants that these devices are fabricated from one or more of the foregoing material specifications. No other warranties, express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog for further information about warranties and limitations of liability. To achieve best results and unless stated otherwise in another Medtronic Sofamor Danek document, do not use any of the DYNALOK CLASSIC™ Spinal System components with the components from any other system. (NOTE: In addition to the DYNALOK CLASSIC™ rod bolt connectors and bolts, a surgeon may want to connect a spinal rod to CD HORIZON® hooks. The hooks would be applied as stated in the CD HORIZON® Spinal System package insert. However, instead of using the fixed angle CD HORIZON® bone screws or multi axial screws, the DYNALOK CLASSIC™ rod bolt connector and bolt would be substituted in their place. Hooks may only be used posteriorly and provided that the metal alloys are compatible.)

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The purpose of this submission is to add closed rod/bolt connectors, TSRH® Spinal System set screws and additional DYNALOK CLASSIC™ bolt lengths to the existing system.

- VI. Indications for Use:** When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the DYNALOK CLASSIC™ Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the DYNALOK CLASSIC™ Spinal System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the DYNALOK CLASSIC™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

When used as an anterolateral thoracic/lumbar system, the DYNALOK CLASSIC™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

- VII. Functionality & Safety Testing:** A Risk Analysis was performed on the DYNALOK CLASSIC™ Spinal System and is included in this submission. The subject DYNALOK CLASSIC™ devices were found to be substantially equivalent to the DYNALOK CLASSIC™ Spinal System.



DEC 13 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Richard Treharne, Ph.D.
Senior Vice President Regulatory Affairs
Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K023415

Trade/Device Name: DYNA-LOK™ CLASSIC Spinal System
Regulation Number: 21 CFR 888.3050, 888.3060, and 888.3070
Regulation Name: Spinal interlaminar fixation orthosis, Spinal intervertebral body fixation orthosis, and Pedicle screw spinal system
Regulatory Class: II
Product Code: KWP, KWQ, MNH and MNI
Dated: November 12, 2002
Received: November 14, 2002

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

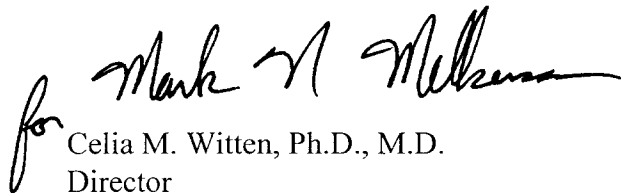
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Richard Treharne, Ph.D.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Mark M. Melkman

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K023415Device Name: DYNALOK CLASSIC™ Spinal System**Indications for Use:**

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the DYNALOK CLASSIC™ Spinal System is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the DYNALOK CLASSIC™ Spinal System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

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When used as an anterolateral thoracic/lumbar system, the DYNALOK CLASSIC™ Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

for Mark N. Millerson
 (Division Sign Off)
 Division of General, Restorative
 and Neurological Devices

Concurrence of CDRH, Office of Evaluation (ODE)

510(k) Number K023415

Prescription Use _____
 (Per 21 CFR 801.109)
 (Optional 1-2-96)

OR

Over-the-counter Use _____